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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,672	08/31/2001	Victor E. Vandell	P 0282906	7805
909 7590 06/06/2007 PILLSBURY WINTHROP SHAW PITTMAN, LLP P.O. BOX 10500 MCLEAN, VA 22102				
			EXAMINER RAMACHANDRAN, UMAMAHESWARI	
			ART UNIT 1617	PAPER NUMBER
			MAIL DATE 06/06/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/942,672

Applicant(s)

VANDELL, VICTOR E.

Examiner

Umamaheswari Ramachandran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 26 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-18,20,25,26 and 29-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-18,20,25,26 and 29-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner notes the receipt of the amendments and remarks received in the office on 3/26/2007 amending claims 10, 12, 20 and 26 and adding new claims 29-33. Claims 3, 19, 21-24, 27 and 28 have been canceled. Claims 1-2, 4-18, 20, 25-26, 29-33 are pending.

Applicants' arguments regarding rejection of claims 1, 2, 4-18 under U.S.C 103 as being unpatentable over Kaplan (US 4,052,513) in view of Smith (US 5,874,074) and further in view of Castillo (US 5,993,836) has been fully considered but they are not persuasive. Accordingly, the rejections of the claims 1, 2, 4-18 are being maintained. Applicants' arguments regarding rejection of claims 20, 25 under U.S.C 103 as being unpatentable over Jackson (US 6,461,644) in view of Smith (US 5,874,074) have been fully considered but they are not persuasive. Accordingly, the rejections of the claims 20, 25 are being maintained. Applicants' arguments regarding rejection of claims 20, 25, 26 as being unpatentable over Castillo (U.S. 5,993,836) in view of Kaplan (U.S. 4,052,513) and Smith (U.S. 5,874,074) have been fully considered but they are not persuasive. Accordingly, the rejections of the claims 20, 25, 26 are being maintained. The limitations of amended claim 20 and additional new claims 29-33 fall within the scope of the rejected claims and hence have been rejected under the same 35 U.S.C 103 rejections that was made in the previous office action (non-final rejection). In view of applicants' amendments and addition of new claims modified 35 U.S.C 103(a) rejections are now made.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 29 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 29 has a limitation "a hydrophilic copolymer" which is new matter and does not have support in the specification. The specification (p 2, lines 25-30) teach that "the formulation is prepared by first mixing the topical anesthetic, solubilizer, homopolymers and copolymers together and heating the mixture at about 80° C while stirring (p 6, para 0024) and further teach in examples, 2-pyrrolidinone, 1-ethenylhexadecyl homopolymer (PVP/1-Hexadecene) (p 7 para 0029). The specification teaches in general homopolymers and is enabled for a hydrophobic polymer such as PVP/1-Hexadecene and does not teach or support the addition of hydrophilic copolymers in the composition.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

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to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4-18, 29, 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan (US 4,052,513) in view of Smith (US 5,874,074) and further in view of Castillo (US 5,993,836).

Kaplan teaches topical oil-in-water emulsions containing, in an oil phase, 0.5-15% of benzocaine solubilized in ester solubilizers of the instant invention. See Abstract; col. 1, lines 45-60; Example I. These solubilizers are used in concentration of 5-40% and impart desirable emollient properties to the compositions. See col. 1, lines 30-44, 56-60. The compositions of Kaplan may contain polyethylene glycol (a hydrophilic monomer), polyethylene glycol esters having MW of 200-600, thickeners such as xanthan gum, viscosity control agents such as paraffin and other cosmetic materials. See col. 2. The examples (I-III) teach the addition of benzocaine in the solid form and hence benzocaine is added in the crystalline form for the formulation preparation.

The reference does not teach copolymers and plant oils of the instant claims.

Smith teaches using PVP/hexadecane copolymer (Ganex V-216) as well as other PVP copolymers such as PVP/dimethylaminoethylmethacrylate (Copolymer 937, Copolymer 958, GAF Corp.) a hydrophilic copolymer as barrier polymers "to form an occlusive or semi-occlusive film-like barrier on the surface of the skin to prevent evaporative loss of moisture from the skin, and protect the skin against environmental irritants" in topical formulations. See col. 4, lines 5-28. Further, the compositions of

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Smith may contain 0.05-1.5% of floral oils as fragrances "for cosmetic purposes." See col. 6, lines 35-48.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Kaplan such that to employ PVP copolymers such as PVP/hexadecane copolymer or hydrophilic copolymer PVP/dimethylaminoethylmethacrylate copolymer. One having ordinary skill in the art would have been motivated to do this to obtain an occlusive or semi-occlusive film-like barrier on the surface of the skin to prevent evaporative loss of moisture from the skin, and protect the skin against environmental irritants as suggested by Smith. Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Kaplan such that to employ floral oils. One having ordinary skill in the art would have been motivated to do this to obtain fragrancng effect as suggested by Smith.

Kaplan and Smith do not teach anhydrous compositions of the instant claims.

Castillo teaches topical, transdermal anesthetic compositions comprising topical anesthetics incorporated within a lipophilic base (See Abstract). Castillo teaches that by using a lipophilic vehicle rather than an oil-in-water delivery system, the formulation is markedly improved in stability". See col. 3, lines 62-64.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Kaplan in view of Smith such that to employ anhydrous lipophilic carrier instead of oil-in-water delivery system. One having

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ordinary skill in the art would have been motivated to do this to obtain improved stability of the formulation as suggested by Castillo.

Claims 20, 25, 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson et al. (US 6,461,644) in view of Smith (US 5,874,074), both of record.

Jackson et al. teach anesthetizing polymer systems comprising a hydrophobic polymer (e.g. polyvinyl chloride, "PVC"), a topical anesthetic such as lidocaine base, prilocaine base and/or tetracaine, and a solubilizer for the topical anesthetic (e.g. isopropyl alcohol). See Abstract; col. 15, lines 50-62; Examples. Jackson et al. teach that lidocaine base and prilocaine base form an oily liquid mixture. See col. 15, lines 50-55. The delivery systems of Jackson et al. may also include fatty alcohols such as lauryl alcohol or oleyl alcohol. See col. 15, line 49; col. 16, lines 33-37; col. 21, Example 9. The anesthetizing polymer systems of Jackson et al. may be used as transdermal patches for providing an anesthetizing effect for hair removal procedures such as laser, waxing or electrolysis. See col. 20, Example 6; col. 31, lines 34-42. Jackson et al. teach applying lidocaine and polymer-containing transdermal patch (layer) to the site to be treated, leaving it on for a sufficient time to produce an anesthetizing effect, and then removing the patch (layer) from the skin. See col. 20, Example 6. Jackson et al. applied as above. The reference teaches in example 1 the addition of solid lidocaine to PVC polymers and hence teaches the addition of crystalline anesthetic lidocaine to the formulation of patches to provide anesthetizing effect for hair removal procedures.

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With respect to Claims 20 and 32, Jackson et al. does not explicitly teach applying the anesthetizing polymer patches (layers) to the scalp or to the hairy area of the scalp. However, the anesthetizing method of Jackson et al. is suitable for removing hair from the skin by laser treatment, waxing or electrolysis, as discussed above. One skilled in the art would reasonably expect that the method of Jackson et al. is suitable for the hair removal from any part of the body, including scalp. Therefore, it would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to modify the anesthetizing method of Jackson et al. such that to use it for hair removal from the scalp. One having ordinary skill in the art would have been motivated to do this because the method produces a sufficient block to withstand the treatment without pain, as suggested by Jackson et al. (see Examples).

The Jackson et al. reference does not teach the claimed plant extract oil.

Smith teach using floral oils as fragrances "for cosmetic purposes" in his topical anesthetic compositions. See col. 6, lines 35-48.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Jackson et al. such that to employ floral oils for their art-recognized purpose. One having ordinary skill in the art would have been motivated to do this to obtain fragrancng effect as suggested by Smith.

Claims 20, 25-26, 31, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castillo (US 5,993,836) in view of Kaplan (US 4,052,513) and Smith (US 5,874,074), all of record.

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Castillo teaches topical, transdermal anesthetic compositions comprising topical anesthetics incorporated within a lipophilic base. See Abstract. As lipophilic material, a mineral oil thickened with polyethylene can be used. See col. 5, lines 31-42. The topical anesthetic compositions of Castillo are applied to the skin of a patient and the compositions are left on the skin for 30-45 minutes or longer for the anesthetic to take effect.

The Castillo reference does not teach the solubilizer and plant extract oil of the instant claims.

Kaplan's teachings discussed as above. Kaplan teaches topical compositions containing, in an oil phase, 0.5-15% of benzocaine solubilized in ester solubilizers of the instant invention. See Abstract; col. 1, lines 45-60; Example I. These solubilizers are used in concentration of 5-40% and impart desirable emollient properties as well as improved stability to the compositions. See col. 1, lines 30-44, 56-60.

Smith's teachings discussed as above. Smith teach using floral oils as fragrances "for cosmetic purposes" in his topical anesthetic compositions. See col. 6, lines 35-48.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Castillo such that to employ ester solubilizers for anesthetic agents. One having ordinary skill in the art would have been motivated to do this to obtain beneficial emollient properties as well as improved stability of the formulation as suggested by Kaplan. Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Castillo such that to employ floral oils for their art-recognized purpose.

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One having ordinary skill in the art would have been motivated to do this to obtain fragrancng effect as suggested by Smith. With respect to the claimed step of applying the composition to the scalp (vs. skin), or hair treatment, the recitation of scalp does not patentably distinguish the instantly claimed method from that taught in the prior art because (1) scalp is skin and (2) it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the composition and method of Castello on any part of the body covered with skin, including scalp, for obtaining desensitizing and anesthetic effect. Hence one of ordinary skill in the art would have been motivated to use the composition in the hair treatment as claimed in claim 32 to obtain desensitizing and anesthetic effect as taught by Castello. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicants' argue that Kaplan, Smith and Castillo do not disclose, suggest or teach the combination of Applicants' claims. In response, Kaplan teaches a composition comprising an anesthetic solubilized in ester solubilizers of the instant invention and Smith teaches a lotion comprising an anesthetic and copolymers. Smith also teaches the addition of floral oils for fragrant purposes in cosmetics. Castillo clearly teaches the anhydrous topical composition comprising an anesthetic which contains no or substantially no, aqueous component or aqueous functional equivalent (col. 4, lines 19-22) and teaches that by using a lipophilic vehicle rather than an oil-in-water delivery system, the formulation is markedly improved in stability (col. 3, lines 62-64). The

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reference further teaches that the lipophilic materials include petrolatum, mineral oil, waxes etc. (col. 5, lines 31-41). The reference teaches that the patient experienced desensitization and good anesthetization after the application of the composition to the skin (example 2). The references combined teach the composition claimed in the instant invention and therefore, the invention, as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Applicants' argue that Jackson teaches transdermal patches comprising anesthetic and polymer PVC but do not suggest that patch applied to the skin would be effective when applied to the scalp. As mentioned earlier, the recitation of scalp does not patentably distinguish the instantly claimed method from that taught in the prior art because (1) scalp is skin and (2) it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the composition and method of Castello on any part of the body covered with skin, including scalp, for obtaining desensitizing and anesthetic effect.

Conclusion

No Claims are allowed.

Applicant's amendment and the addition of new claims necessitated the modified rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

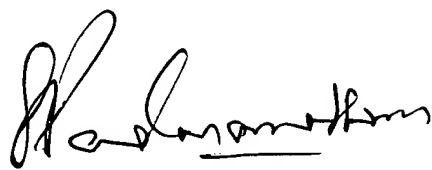
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